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Defendants Colgate-Palmolive Co. ("Colgate") and Tom's of Maine, Inc. ("Tom's") (collectively, "Defendants") submit the following Memorandum of Points and Authorities in support of their Motion to Stay Action:

INTRODUCTION AND RELEVANT FACTUAL BACKGROUND

In November 2015, the U.S. Food and Drug Administration (the "FDA") opened a pre-rulemaking docket to obtain information and comments regarding the "Use of the Term 'Natural' in the Labeling of Human Food Products." See 80 Fed. Reg. 69905 (Nov. 12, 2015) (the "Request"), Ex. 1. Since the FDA's announcement, courts in this jurisdiction and elsewhere have stayed "natural" cases based on the primary jurisdiction doctrine, which counsels courts to defer to agencies (including the FDA) when they are faced with issues that have been placed within the agency's regulatory ambit. See, e.g., Kane v. Chobani, LLC, 645 Fed. Appx. 593, 594 (9th Cir. 2016); Viggiano v. Johnson & Johnson, 2016 WL 5110500, at *1-2 (C.D. Cal. 2016); see also In re KIND LLC "Healthy and All Natural" Litig., 209 F.Supp.3d 689, 696-97 (S.D.N.Y. 2016). Defendants ask this Court to do likewise. See disc. infra at 4-9.

Colgate and its subsidiary Tom's manufacture, market, sell and distribute personal care products under the Tom's of Maine brand. See, e.g., Tom's, "Heritage," http://www.tomsofmaine.com/company (last visited June 2, 2017), Ex. 2. Tom's has been in business for nearly 50 years and is well known for highquality, sustainable and responsible personal care products. See id. In its marketing, Tom's attempts to be completely transparent about the ingredients in its products as well as the basis for the labeling of any particular product as "natural." See, e.g., Tom's, "What's Not in Our Products," http://www.tomsofmaine.com /products/overlay/Not-In-Our-Products (last visited June 2, 2017), Ex. 3. Tom's

All exhibits are attached to the Declaration of Kathleen P. Lally, which is being submitted concurrently herewith.

1 website contains a detailed discussion of what it means, for example, when a Tom's product indicates that it is "[n]aturally [s]ourced and [d]erived" and what 2 3 processes Tom's does and does not find acceptable. See, e.g., Tom's, "Ingredients," http://www.tomsofmaine.com/products/ingredient-list (last visited 4 June 2, 2017), Ex. 4. And the labels of Tom's products explain what makes Tom's 5 products "natural and good" and encourage consumers to visit its website to "learn 6 7 more about . . . what 'natural' means for Tom's of Maine ingredients and their 8 processing." See, e.g., Tom's "Children's Toothpaste" Label, Ex. 5. 9 Despite this transparency, Plaintiff Schuyler White ("Plaintiff") filed suit 10 against Defendants on February 1, 2017 alleging that Defendants made false and 11 misleading "natural" claims regarding Tom's product line to sell the products at a 12 premium price, despite Defendants' purported knowledge that the products are not 13 natural. See Amd. Compl. (Dkt. No. 22) ¶¶ 1-4. Plaintiff asserts causes of action 14 for negligent misrepresentation, breach of express and implied warranties, and 15 violations of California consumer protection laws on behalf of a proposed 16 nationwide class of consumers who purchased Tom's products on or after 17 September 24, 2015, as well as a California subclass. See id. ¶¶ 34-35, 46-104. 18 Before Plaintiff filed his Amended Complaint, however, the FDA – which 19 Congress has tasked to consider and regulate the key issue in this case – opened the 20 Request for information and comments regarding the use of the term "natural" in 21 the labeling of food products. See Request, Ex. 1. This inquiry is not merely 22 related to, but was caused by the proliferation of lawsuits regarding "natural" 23 labeling. See, e.g., Amd. Compl. (Dkt. No. 22) at passim; see also Request, Ex. 1 24 at 69905. The FDA has solicited comments and proposals from the public and 25 industry groups on the issues raised in the Amended Complaint, including what 26 types of ingredients would disqualify a product from bearing the term "natural" 27 and whether the manner in which an ingredient is produced or sourced should

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affect whether a product containing the ingredient may be labeled as "natural."

See Request, Ex. 1 at 69908. The notice and comment period ended in May 2016, with the FDA receiving over 7,600 comments from consumers, companies, food experts and health and legal authorities. See FDA, "Use of the Term 'Natural' in the Labeling of Human Food Products," Docket Folder Summary, https://www.regulations.gov/docket?D=FDA-2014-N-1207 (last visited June 2, 2017), Ex. 6. The FDA will use the information provided by the public comments to "formulate the specific policy to be put forth in a subsequent proposed rule." See FDA, "Rules and Regulations," https://www.fda.gov/regulatoryinformation/rules regulations/ (last visited June 2, 2017), Ex. 7.

Following the FDA's announcement, courts have stayed "natural" cases based upon the primary jurisdiction doctrine, and deferred to the FDA on the "natural" issue that Congress has placed within the FDA's regulatory authority.

See, e.g., Kane, 645 Fed. Appx. at 594; Viggiano, 2016 WL 5110500, at *1-3; see also In re KIND LLC, 209 F.Supp.3d at 695-97. Staying Plaintiff's action under the primary jurisdiction doctrine will allow this Court to benefit from the FDA's guidance on a key issue in this litigation as well as ensure uniformity and consistency in an area Congress has entrusted to the FDA to regulate. See Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753, 761 (9th Cir. 2015); disc. infra at 4-9.

II. GOVERNING LEGAL STANDARD

The primary jurisdiction doctrine counsels judicial deference to an agency "whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body[.]" <u>United States v. W. Pac. R.R. Co.</u>, 352 U.S. 59, 63-64 (1956). Primary jurisdiction ensures "[u]niformity and consistency in the regulation of business entrusted to a particular agency" and allows courts to "more rationally" exercise judicial review by deferring to agencies "that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure." <u>See Writers Guild of Am., W., Inc. v. ABC., Inc.</u>,

609 F.2d 355, 363 (9th Cir. 1979) (citing Far E. Conference v. United States, 342 1 2 U.S. 570, 574-75 (1952)). 3 In evaluating primary jurisdiction, courts in the Ninth Circuit consider: (1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in 4 5 6 administration. 7 Syntek Semiconductor Co. v. Microchip Tech., Inc., 307 F.3d 775, 781 (9th Cir. 8 2002). The FDA's active involvement in addressing the labeling issues raised by 9 Plaintiff's "natural" claims is sufficient to satisfy the foregoing elements and 10 weighs strongly in favor of a stay in this case. See id.; disc. infra at 4-9. 11

III. **ARGUMENT**

Given the FDA's Request and forthcoming guidance on the use of "natural," the case for staying Plaintiff's "natural" claims on primary jurisdiction grounds is straightforward. See Swearingen v. Late July Snacks LLC, 2014 WL 2215878, at *3 (N.D. Cal. 2014) (holding primary jurisdiction applied to false advertising claims challenging the "evaporated cane juice" ingredient while the FDA is "actively considering an issue central to the litigation"); disc. <u>infra</u> at 4-9.

A. The FDA Is Currently Reviewing And Deciding This Very Issue

The first criteria for determining whether a case should be stayed pursuant to the doctrine of primary jurisdiction (i.e., the need to resolve an issue) is easily met in the case. As noted above, the FDA has initiated proceedings to offer guidance on whether certain products "may be labeled as 'Natural,' 'All Natural,' and/or '100% Natural.'" See Request, Ex. 1 at 69907; see also disc. supra at 1-3. While the FDA's review covers "natural" labeling in the context of food products, there is no indication that the FDA's pending guidance would not also apply to personal care and cosmetic products. See Request, Ex. 1. at 69908 (noting that the FDA sought comments regarding what types of ingredients would disqualify a product from bearing the term "natural" and whether the manner in which an ingredient is

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produced or sourced should affect whether a product containing the ingredient may be labeled as "natural").

Regardless, the FDA's guidance on the use of "natural" in food products would certainly be instructive in this case. See Kane, 645 Fed. Appx. at 594 (addressing "natural" labels); Viggiano, 2016 WL 5110500, at *1-2 (same). Indeed, the Ninth Circuit affirmed the district court's order invoking the FDA's primary jurisdiction and stayed a case involving "natural" labels for cosmetic products, noting that it was not unreasonable for the district court to think "new guidance" regarding "natural" would be "forthcoming" in light of "a flurry of litigation over food labeling." See Astiana, 783 F.3d at 761.²

B. Labeling Standards Are Uniquely Within The FDA's Authority and Discretion

Not only is the decision regarding what constitutes a "natural" product uniquely within the expertise of the FDA, but it also has authority over the issues of product labeling standards. Even before the FDA announced its intent to delve into these issues, courts held that the use of the term "natural" fell within the FDA's discretion. See, e.g., Astiana, 783 F.3d at 761; Cox v. Gruma Corp., 2013 WL 3828800, at *2 (N.D. Cal. 2013) (holding that "deference to the FDA's regulatory authority is the appropriate course"). In Astiana, for example, the Ninth Circuit held that "[d]etermining what chemical compounds may be advertised as natural on cosmetic product labels is 'a particularly complicated issue that Congress has committed' to the FDA," and therefore, "[o]btaining expert advice

In addition, the FDA received comments addressing the possibility of overlap between the use of the term "natural" in food products and in personal care and cosmetic products, indicating that the FDA's guidance may have some applicability to personal care and cosmetic products. See, e.g., Consumer Healthcare Products Association, Comment (May 10, 2016) (suggesting that there should be a distinction between natural food products and other natural products), Ex. 8; Robin Rogers, Comment (Nov. 24, 2015) (arguing that consumers need definitions for "natural" that apply to products applied to the skin, hair, and lips), Ex. 9.

from that agency would help ensure uniformity in administration of the 1 comprehensive regulatory regime established by the FDCA." Astiana, 783 F.3d at 3 761. 4 Indeed, the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") 5 empowers the FDA to set forth labeling requirements and to prohibit labels that are 6 "false or misleading in any particular." 21 U.S.C. § 362 (2017); see also In re 7 KIND LLC, 209 F.Supp.3d at 695. In that sense, the issue of whether particular ingredients referenced in Plaintiff's Amended Complaint rendered the "natural" 8 claims on Tom's labels misleading "seems to be particularly within the FDA's 9 10 discretion." In re KIND LLC, 209 F.Supp.3d at 695; 21 U.S.C. § 362. 11 Accordingly, the second and third criteria for a stay pursuant to the primary 12 jurisdiction doctrine have also been met. 13 C. **Determining What Constitutes A "Natural" Product Is A Highly** 14 Technical Issue Better Left To The Expertise Of The Agency 15 The next criteria for primary jurisdiction (i.e., whether the need to resolve an issue requires expertise or uniformity in administration) is also easily satisfied. 16 17 Courts in the Ninth Circuit and elsewhere have recognized that determining what 18 qualifies as "natural" does not fall within the typical experience or expertise of 19

judges. See, e.g., Astiana, 783 F.3d at 760 ("Without doubt, defining what is 'natural' for cosmetics labeling is [] within the FDA's expertise[.]"); Forsher v. J.M. Smucker Co., 2016 WL 5678567, at *2 (E.D.N.Y. 2016) (noting that "many courts have found that the technical and policy issues raised by ['natural'] claims are better suited to being addressed by the FDA rather than the courts"). As the Ninth Circuit noted:

The delineation of the scope and permissible usage of the term[] natural ... in connection with food products implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than the judicial branch.

Kane, 645 Fed. Appx. at 594 (internal citation and quotations omitted).

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The FDA, moreover, "employs . . . chemists . . . and numerous other specialists in order to address public health and safety issues," resources not readily available to the courts. See Coyle v. Hornell Brewing Co., 2010 WL 2539386, at *4 (D.N.J. 2010). And, as noted above, the FDA has gathered extensive comments and information from consumers and industry groups to support the analysis by the FDA's experts. As such, determining what qualifies as "natural" is a decision uniquely within the expertise of the agency, not the courts. See, e.g., Kane, 645 Fed. Appx. at 594.

D. There Is A Substantial Danger Of Inconsistent Rulings If Individual Courts Make Differing Determinations Regarding "Natural" Labeling

The final criteria for primary jurisdiction is also satisfied because the question of what constitutes a "natural" product requires uniformity in administration. See, e.g., Astiana, 783 F.3d at 761. Allowing individual courts to make judicial determinations as to the appropriate definition for "natural" would result in differing decisions and requirements – on a case-by-case and product-by-product basis – that would make uniform labels impossible. See In re KIND LLC, 209 F.Supp.3d at 695-96 (finding substantial danger of inconsistent rulings if stay not granted in light of FDA's pending "natural" guidance). In fact, it is "easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged [] products," as "[m]anufacturers might have to print out 50 different labels[.]" Turek v. Gen. Mills, Inc., 662 F.3d 423, 426 (7th Cir. 2011).

And in this case, the risk of inconsistent decisions is particularly acute – before Plaintiff filed the instant case, plaintiffs Anne de Lacour, Andrea Wright and Loree Moran filed a complaint against Defendants in the Southern District of New York. See First Amd. Compl. (Dkt. No. 8), de Lacour, et al. v. Colgate-Palmolive Co. and Tom's of Maine, Inc., No. 1:16-cv-08364-RA (S.D.N.Y. 2016) ("de Lacour"), Ex. 10. Like Plaintiff, the plaintiffs in de Lacour seek to represent a

nationwide class, along with a class of California consumers. Id. at ¶¶ 33-34. The de Lacour complaint makes similar allegations as those in this case; specifically, that Defendants allegedly made false and misleading "natural" claims regarding Tom's products in order to sell Tom's products at a premium price. See id. ¶¶ 1-4. The de Lacour plaintiffs assert causes of action for breach of express warranty and violations of California, Florida and New York consumer protection laws on behalf of a proposed nationwide class of consumers who purchased Tom's products on or after September 24, 2015, as well as certain subclasses. See id. at ¶¶ 46-132.

The fact that two nearly identical complaints are pending against Defendants in two different jurisdictions creates the very real potential for inconsistent judicial rulings if the cases are not stayed. See, e.g., Taradejna v. Gen. Mills, Inc., 909 F. Supp. 2d 1128, 1135 (D. Minn. 2012) (noting need for uniform rulings where "lawsuits throughout the country involve the same or similar issues as found in the instant suit"). Discordant rulings, moreover, could force Tom's to print different labels on a jurisdiction-by-jurisdiction basis, or even worse, subject it to conflicting standards in states covered by Plaintiff's claims. See, e.g., In re KIND LLC, 209 F.Supp.3d at 695-96; Turek, 662 F.3d at 426. Deferring to the expertise of the FDA will avoid this impractical result and help ensure uniformity of the FDA's regulatory regime. See, e.g., Astiana, 783 F.3d at 761.

Defendants are concurrently moving for a stay in <u>de Lacour</u>.

The fact that this case was filed after <u>de Lacour</u> is a separate basis for a stay under this Court's inherent authority to stay proceedings. <u>See</u>, <u>e.g.</u>, <u>Palomar Techs.</u>, <u>Inc. v. Mrsi Sys.</u>, <u>LLC</u>, 2016 WL 4496839, at *1 (S.D. Cal. 2016) ("[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the cases on its docket with economy of time and effort for itself, for counsel, and for litigants."). Moreover, where, as here, a similar complaint had already been filed in another federal court (<u>i.e.</u>, <u>de Lacour</u>) when Plaintiff filed his complaint, this Court may stay the second-filed action (<u>i.e.</u>, <u>White</u>) under the "first to file" rule. <u>See Meints v. Regis Corp.</u>, 2010 WL 625338, at *2 (S.D. Cal. 2010). Application of the "first to file" rule does not require identical parties, but rather "substantially similar" cases. <u>See id.</u> (internal citation omitted). Given the overlap of the putative classes and claims, <u>de Lacour</u> and <u>White</u> are "substantially similar" and this Court could also issue the stay under the

E. Any Potential Delay Does Not Outweigh The Need For The FDA's Expertise

Although the Supreme Court has never expressly held that courts should weigh efficiency concerns against other factors relevant to primary jurisdiction, see Ellis v. Tribune Television Co., 443 F.3d 71, 90 (2d Cir. 2006), the Ninth Circuit has discussed judicial economy in its primary jurisdiction opinions. See Astiana, 783 F.3d at 761 (noting primary jurisdiction is not required "when a referral to the agency would significantly postpone a ruling that a court is otherwise competent to make"). Defendants' argument for a stay is stronger here because the FDA has already completed its notice and comment period, a necessary step that will inform the FDA's guidance, and seems determined to address the "natural" labeling issue. See Kane, 645 Fed. Appx. at 594 ("Given the ongoing FDA proceedings regarding the term[] 'natural' . . . we conclude that resolution of this action will not be needlessly delayed and that judicial resources will be conserved by staying these proceedings."); In re KIND LLC, 209 F.Supp.3d at 696-97.

IV. <u>CONCLUSION</u>

For the reasons set forth above, Defendants respectfully request that this Court stay this action in its entirety on the grounds of primary jurisdiction.

Dated: June 2, 2017 Respectfully submitted,

21 LATHAM & WATKINS LLP

22 By: s/Kathleen P. Lally
Kathleen P. Lally

26 "first to file" rule. See id. at *3 (granting stay of putative class action

[&]quot;first to file" rule. <u>See id.</u> at *3 (granting stay of putative class action when settlement in competing class action would bar putative class action).

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